

Application No. 10/603,397

REMARKS

Claims 10-12 are pending. Applicant respectfully acknowledges the withdrawal of the prior final rejections based on Morita. By this amendment, claim 10 has been amended to clarify the inherent scope of the claimed invention. No new matter is added. New claims 14-22 have been added with independent claim 14 presenting subject matter claimed in the means-plus-function format provided for by Section 112. Support for the present amendment and new claims can be found throughout the specification and claims as originally filed. No new matter has been introduced by way of the present amendment.

Interview Summary

The applicants and their attorney thank the Examiner and his supervisor for the courtesy extended during the interview at the PTO on March 8, 2006. The substance of the interview is accurately reflected in the Interview Summary prepared by the Examiner at the end of the Interview. The substance of the proposed response and the discussions at the interview are also embodied in this Amendment and Response.

35 U.S.C. § 102 Rejection

In the Office Action of November 1, 2005, claims 10-12, were rejected under 35 U.S.C. § 102(b) as being unpatentable over United States Patent No. 2,283,814 to LaPlace. In addition, claims 10-12 were rejected under 35 U.S.C. § 102(b) as being unpatentable over United States Patent No. 3,757,629 to Schneider. These rejections are respectfully traversed.

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As indicated in the summary of the interview and consistent with the inherent scope of the claimed invention, the applicants have amended independent claim 10 to expressly recite the limitation of bioabsorbable in the body of the claim instead of the preamble to make clear that the scope of the claimed invention of independent claim 10 covers a bioabsorbable staple body.

Applicant notes that Schneider was previously disclosed in an IDS submission and is expressly discussed within the Background of the Invention section of the present application. The inclusion of Schneider as part of a listed set of prior art bioabsorbable staple patents was an inadvertent oversight, and the applicants expressly disclaim any implied admission that Schneider teaches or suggests the use of a bioabsorbable plastic material for the staple body. Accordingly, the applicants have amended the Background of the Invention to correct this oversight.

Contrary to the statements made about the set of prior art bioabsorbable staple patents in the Background of the Invention that these prior art bioabsorbable staples were expressly designed not to deform, and consistent with the characterization set forth in the Office Action, Schneider is designed to deform immediately upon insertion; however, Schneider is not designed to deform in the manner or to the limitations as required by the claims of the present invention and not where such deformation is a designed function of a bioabsorbable material that comprises the staple body.

"For a prior art reference to anticipate in terms of 35 U.S.C. § 102, every element of the claimed invention must be identically shown in a single reference." *In re Bond*, 15 U.S.P.Q. 2d 1566, 1567 (Fed. Cir, 1990). "Every element of the claimed invention must be literally present, arranged as in the claim. The identical invention must be shown in as complete detail as is

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contained in the patent claim." *Richardson v. U.S. Suzuki Motor Corp.*, 9 U.S.P.Q. 2d 1913, 1920 (Fed. Cir. 1989); see also MPEP § 2131.

Neither LaPlace nor Schneider disclose a bioabsorbable staple body with cleats at the end of each arm that is clearly the subject matter of the claimed inventions. LaPlace discusses the use of sheet metal stock or wire (col. 3, lines 20-30), while Schneider discloses the use of resilient plastic material having an elastic memory (col. 1, lines 42-45; col. 2, lines 32-35). As Schneider describes one of the objects of the invention to be to provide an inexpensive non-metallic fastener (col. 1, lines 49-51) and describes use of the fastener in joining packaging materials, insulating materials and construction materials, it is clear that Schneider does not disclose the use of expensive, bioabsorbable materials as presently claimed.

In addition to lacking any disclosure relative to the use of a bioabsorbable material for the staple body, neither LaPlace nor Schneider disclose shoulder angles for a first position and second position as presently claimed. While both LaPlace and Schneider illustrate shoulder angles for the claimed first position, neither LaPlace nor Schneider describe a staple wherein these shoulder angles transition to a second position in response to "forces exerted by living tissue wound and deformation of at least the shoulder portions of the bioabsorbable staple body caused by polymeric creep and absorption of the bioabsorbable staple body in the living human tissue."

In response to the discussion with the Examiner and SPE Dawson at the interview, the applicants have amended claim 10 in order to more clearly describe the combination of factors that influence the deformation of the bioabsorbable staple body of the invention of independent claim 10. Support for the specific nature of the lateral forces (denoted as 216 in Figs. 20 and 21)

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and of the polymeric creep and absorption of the bioabsorbable polymer material is set forth in the paragraph [0063] of the specification. With the clarification to the claim language, it is respectfully submitted that claim 10 is clearly not anticipated by either the metal staple of LaPlace or the cheap plastic staple of Schneider that is intended for use with cardboard and other kinds of construction and packaging materials.

As discussed at the interview, applicants are unaware of any bioabsorbable staples intended for medical use that feature staple arms with cleats or elbow portions. Even if there were some motivation to take the teaching of Schneider, for example, and attempt to utilize that teaching in a medical context, it is respectfully submitted that Schneider expressly teaches (i) that the change in position should occur immediately upon insertion and not at some time subsequent to insertion, and (ii) that the divergence that occurs immediately upon insertion would have "[a] suitable range for the angle of divergence of the legs from parallel position [i.e., 90°] [that] will vary from as little as about 1° [i.e., from 89°-91°] to as much as about 25° [i.e., from 65°-115°], dependent upon the plastic material selected and the length of the legs." [Col. 3, lines 24-27] This teaching in Schneider is plainly outside the claimed limitations of "between 120°-180° in a second deformed position" which are required by independent claim 10.

The lack of any relevant teaching in this regard of either LaPlace or Schneider is only further compounded when the additional limitations of dependent claims 11 and 12 are considered, neither of which has any basis for support of a teaching or disclosure in either LaPlace or Schneider.

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As neither LaPlace nor Schneider disclose every element of independent claim 10 or dependent claims 11 and 12 as discussed above, none of these claims are anticipated by LaPlace or Schneider. Applicant respectfully requests said rejections be withdrawn.

CONCLUSION

In view of the foregoing, it is submitted that this application is in condition for allowance. Favorable consideration and prompt allowance of the application are respectfully requested. The Examiner is invited to telephone the undersigned if the Examiner believes it would be useful to advance prosecution.

Respectfully submitted,



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